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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,956	10/05/2007	Hyun-Ah Kang	HANOL-13037	2242
72960	7590	02/24/2009		
Casimir Jones, S.C. 440 Science Drive Suite 203 Madison, WI 53711			EXAMINER RAGHU, GANAPATHIRAM	
			ART UNIT	PAPER NUMBER
			1652	
			MAIL DATE	DELIVERY MODE
			02/24/2009	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/587,956

**Applicant(s)**

KANG ET AL.

**Examiner**

GANAPATHIRAMA RAGHU

**Art Unit**

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-11 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

***Detailed Action***

Claims 1-11 are pending.

***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

The inventions listed in claim 1-11 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following categories:

- 1) A product and a process specially adapted for the manufacture of said product; or
- 2) A product and process of use of said product; or
- 3) A product, a process specially adapted for the manufacture of said product and a use of said product; or
- 4) A process and an apparatus or means specifically adapted for carrying out the said process; or
- 5) A product, a process specially adapted for the manufacture of said product and an apparatus or means specifically designed for carrying out the said process.

37 CFR 1.475(c) states: If an application contains more or less than one of the combination of categories of in an invention set forth in paragraph (b) of this section, unity of invention might not be present.

In addition, the PCT does not provide for multiple products or methods within single application, therefore, unity of invention is lacking with regard to claims 1-11; see 37 CFR 1.475. 37 CFR 1.475 (d) also states: If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) 1.47(c).

37 CFR 1.475(e) further states; the determination whether a group of invention is so linked as to form a single inventive concept shall be without regard to whether the inventions are claimed in separate claims or as alternative within a single claim.

The inventions listed in claim 1-11 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons: The prior art clearly teaches cloning and characterization of the *Hansenula polymorpha* homologue of the *Saccharomyces cerevisiae* MNN9 gene encoding for  $\alpha$ -1-mannosyltransferase (see Kim et al., Yeast, 2001, Vol. 18: 455-461, entire document) and anticipates claims 1-3 of the instant invention. Therefore, the shared technical feature of these claims, does not constitute a special technical feature as defined in PCT Rule 13.2 as it is not a feature which defines a contribution of the claimed invention makes over the prior art.

***Species Election***

This application contains claims directed to the following patentably distinct species of the claimed invention:

**Claim 7:** The species are as follows:

Wherein the sugar chain-modifying enzyme is selected from:

- a) a-1,2-mannosidase,
- b) mannosidase IA,
- c) mannosidase IB,
- d) mannosidase IC,
- e) mannosidase II,
- f) N-acetyl glucosaminyltransferase I,
- g) N-acetylglucosaminyltransferase II,
- h) galactosyltransferase,
- i) sialyltransferase, and
- j) fucosyltransferase

**Claim 10:** The species are as follows:

Wherein the recombinant glycoprotein is selected from:

- 1) cytokines,
- 2) clotting factors,

- 3) growth factors,
- 4) growth hormone releasing factors,
- 5) angiostatin,
- 6) tissue plasminogen activators,
- 7) plasminogen activator inhibitors,
- 8) urokinase,
- 9) *Bacillus amyloliquefaciens*  $\alpha$ -amylase,
- 10) *Saccharomyces cerevisiae* aspartic protease,
- 11) *Saccharomyces cerevisiae* invertase,
- 12) *Typanosoma cruzi* trans-sialidase,
- 13) HIV20 envelope protein,
- 14) haemagglutinin,
- 15) enterokinase,
- 16) human  $\alpha$ -antitrypsin,
- 17) human antithrombin III,
- 18) erythropoietin,

- 19) herpes virus type-1 glycoprotein, and
- 20) immunoglobulins.

The species of claims 7 and 10 have different functions and different structures and are patentably distinct; searching for all the species would impose a serious search burden. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a specific combination i.e., one sugar chain-modifying enzyme from a)-j) and one glycoprotein from 1)-20) of the disclosed species for prosecution, on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently claims **1-6, 8, 9 and 11** are generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.**

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

#### ***Final Comments***

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages.



It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathirama Raghu whose telephone number is 571-272-4533. The examiner can normally be reached between 8 am-4: 30 pm EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat T. Nashed can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and for After Final communications. Any inquiry of a general nature or relating to the status of the application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Ganapathirama Raghu/  
Patent Examiner  
Art Unit 1652